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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/808,031	03/03/1997	SUMIKO INOUE	377.5888P	5819

35811 7590 01/05/2004

IP DEPARTMENT OF PIPER RUDNICK LLP
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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

B.M.

Office Action Summary**Application No.**

08/808,031

Applicant(s)

INOUYE ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8,10,12 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,10,12 and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicants amendment of the specification, amendment of claims 1, 6, 7 and 15, in Paper of 8/21/2003, is acknowledged. Claims 1, 2, 4-8, 10, 12 and 15-17 are still at issue and are present for examination.

Applicants' arguments filed on 8/21/2003 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

It is further noted that applicants amended set of claims which are supposed to list a complete set of claims, does not accurately recite claim 8 as it should be.

Applicants amendment lists claim 8 as:

8. (Previously Amended) An isolated and purified bacterial RT which comprises an amino acid sequence selected from the sequences SEQ ID Nos: 32-38 shown in Figure 14, which sequences are shown in SEQ ID Nos. 30-36.

The correct copy of claim 8 which was "previously amended" on 12/11/1996 is:

8. (Twice amended) An isolated and purified bacterial RT which comprises an amino acid sequence selected from the sequences SEQ ID Nos: 32-38 shown in Figure 14 [, which sequences are shown in SEQ ID Nos. 30-36].

Note the bracketed phrase [, which sequences are shown in SEQ ID Nos. 30-36] was removed in the amendment of 12/11/1996 and for the purpose of examination this is how the claim has been examined.

Applicants are asked to make sure that the set of claims which applicants submit with any amendment or response is accurate.

Claim Objections

Claim 15 is objected to because of the following informalities:

The newly added recitation in claim 15 recites "...SEQ ID No. 11-24 and 32-38". Applicants should maintain consistency throughout the claims such as "...SEQ ID NO: 11-24 and 32-38".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 5, 6, 12, 15, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claim 1 (claims 2, 4, 5, 6, 12 and 17 dependent on) for being indefinite in that the recitation "of (SEQ ID. 1), or a substantially homologous amino acid sequence..." is unclear was stated in the previous office action and repeated here. First, the use of the parenthesis surrounding SEQ ID. 1 are unclear given the context of the claim in which they are used and it is suggested that they be deleted. Second, SEQ ID NO: 1 is a nucleic acid sequence, not an amino acid sequence. The recitation is interpreted for the purpose of advancing prosecution as "encoded by SEQ ID NO: 1, or a substantially homologous amino acid sequence...". Thirdly, the instant claims are indefinite in the recitation of "substantially homologous " as this phrase is unclear absent

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a statement as to what applicants constitute "substantially homologous". As such it is unclear how homologous to the sequence of a gene encoding SEQ ID NO:1, a sequence must be to be included within the scope of these claims.

In response to this rejection applicants have amended claim 1 and traverse this rejection as it applies to newly amended claim 1 on the following basis. Applicants note that SEQ ID NO: 1 refers to both a nucleic acid and amino acid sequence. While it is admitted that applicants list in the paper copy of the sequence in addition to the nucleic acid sequence of SEQ ID NO: 1, the corresponding encoded amino acid sequence of SEQ ID NO: 2, SEQ ID NO: 1 is a nucleic acid sequence as listed in the descriptor of the sequence (i.e. Sequence Characteristics 1(B) TYPE: nucleic acid). Thus this argument is not found persuasive.

Applicants have not commented in response to the comments regarding the use of parenthesis around SEQ ID NO: 1.

Thus the previous rejection of claim 1 (claims , 2, 4, 5, 6, 12 and 17 dependent on) remains.

Newly amended claim 15 (claim 16 dependent on) is indefinite in that the newly added limitation "...wherein said YXDD box is contained in the group consisting of SEQ ID No. 11-24 and 32-38." is unclear and confusing. It is believed that applicants intent is to limit the claimed reverse transcripts to those which have a YXDD box found in SEQ ID No. 11-24 and 32-38, namely YMDD, YVDD, YLDD, YADD and YCDD, however this is unclear and it is suggested that applicants amend this recitation to clearly designate such. For the purpose of advancing prosecution this recitation is interpreted as further

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limiting the claimed reverse transcripts to those which comprise a YXDD box selected from the group consisting of YMDD, YVDD, YLDD, YADD and YCDD.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15, and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was stated in the previous office action as it applied to previous claims 1, 2, 4-6, 12, 15, 16 and 17. In response applicants have amended claims 1, 6, 7 and 15. Applicants amendment has resulted in the withdrawal of claims 1, 2, 4, 5, 6, 12 and 17.

It is believed that applicants traverse the rejection as it applies to the now amended claims although this is somewhat confusing as applicants do not specifically say that they are traversing the rejection under 35 U.S.C. 112, first paragraph, but merely state "Turning now to a consideration of Claim 15. Since this statement is under the heading for rejections under 35 U.S.C. 112, first paragraph, and there is not a rejection of claim 15 under 35 U.S.C. 112, second paragraph it is assumed that these somewhat brief comments are applicants traversal.

Applicants submit that they have provided additional structural features along with the structural features already contained in claim 15 to demonstrate that applicants were in possession of the claimed reverse transcriptase. Applicants further point to figures 5 and 14 for support of the newly added limitation. Applicants thus conclude that given the inclusion of these sequences and the respective location of their YXDD box, as delineated in Figs 5 and 14, one of skill in the art would readily recognize that applicants were in possession of a prokaryotic reverse transcriptase having a YXDD box conserved among the various prokaryotic organisms.

Applicants argument is not found persuasive, the additional minor limitation that the claimed reverse transcripts must further comprise a YXDD box selected from the group consisting of YMDD, YVDD, YLDD, YADD and YCDD (see above 112 second paragraph rejection) does not further describe the structure to functional relationship of the claimed genus sufficient that one of skill in the art would recognize that applicants were in possession of a prokaryotic reverse transcripts having a YXDD box conserved among the various prokaryotic organisms.

As previously stated, the mere recitation of a four or five amino acid motif or even a number of number of such motifs conserved among a number of bacterial reverse transcripts that are themselves hundreds of amino acids in length is not an adequate structural description. Applicants claim 15 and 16 are drawn to the genus of bacterial reverse transcripts which comprise a YXDD and an Asn-Xaa₁-Xaa₂ motif. As the taught species of this genus are hundreds of amino acids in length, the genus of bacterial reverse transcripts whose only structural limitation is a four and three amino acid motif

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is not adequately described with respect to the structure/function of the claimed genus. Given this lack of an adequate structure to function/activity relationship of the disclosed RT species, the skilled artisan would not recognize applicants were in possession of the claimed genus.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 8, 10, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lim and Mass (Cell 56:891-904, 1989).

The rejection is stated in the previous office actions.

In response to this previous rejection applicants submit that as a result of the amendment to claims 1 and 15, the rejection is obviated, by the removal of the “substantially homologous amino acid sequence” language, and Lim and Mass fail to teach a 485 amino acid open reading frame. Applicants argument is not found persuasive because the reverse transcriptase taught by Lim and Mass meets each of the limitations of the claims, for instance, it is encoded by SEQ ID NO: 1, (See also

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above 112 second paragraph rejection) and thus each of the limitations of the rejected claims are inherent to the RT taught by Lim and Mass.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-8 and 15-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over either of Inouye et al. (US Pat. 5,320,958 or US Pat. 5,434,070), in view of the combination of Rice et al. (July 1993), Xiong et al. (1990) and Hsu et al. (Apr. 1992).

The rejection is stated in the previous office actions.

Applicants have amended claims 1 and 15 in response to this rejection and traverse the rejection as it applies to the newly amended claims. With respect to applicants amendment of claims 1, 2, 4-6 and 17 that the claimed bacterial RT is encoded by SEQ ID NO: 1 (See also above 112 second paragraph rejections), this is considered an inherent property of the bacterial RT for which the original rejection was made, and motivation stated.

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Applicants submit that the current application claims the benefit of both U.S. Patents '958 and '070 and that the inventors own prior work can not be cited as part of prior art to show that the later invention is obvious under 103.

Applicants above comments are acknowledged. If it is applicants intention to overcome this rejection by the filing of a declaration, then applicants are referred to the MPEP 2132.

Applicant's disclosure of his or her own work within the year before the application filing date cannot be used against him or her under 35 U.S.C. 102(a). In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982) (discussed below).

Therefore, where the applicant is one of the co-authors of a publication cited against his or her application, the publication may be removed as a reference by the filing of affidavits made out by the other authors establishing that the relevant portions of the publication originated with, or were obtained from, applicant. Such affidavits are called disclaiming affidavits. Ex parte Hirschler, 110

USPQ 384 (Bd. App. 1952). The rejection can also be overcome by submission of a specific declaration by the applicant establishing that the article is describing applicant's own work. In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982).

However, if there is evidence that the co-author has refused to disclaim inventorship and believes himself or herself to be an inventor, applicant's affidavit will not be enough to establish that applicant is the sole inventor and the rejection will stand. Ex parte Kroger, 219 USPQ 370 (Bd. Pat. App. & Int. 1982) (discussed below). Applicants submit that the combination of the above references is a result of hindsight construction that uses an "obvious to try" standard.

Applicants are reminded of those comments regarding this issue and this rejection in the office action of 11/16/2001 which stated:

In the original 103 rejection of these claims it was noted by the examiner that the instant application receives the benefit of the filing date only of June 30, 1994, for subject matter of RT's from any organism other than *E.coli.* and *M. xanthus.* Applicants are reminded that it is not the issue date of the above U.S. Patents that is important, when swearing behind said patents, but rather the filing date, which precedes the priority date for the instant application, as well as the date of the submitted 1.131 declaration. Further applicants are reminded that a properly executed 1.131 declaration must be signed by all inventors/applicants.

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Applicants further traverse the rejection on the basis that simply because one of skill in the art may be aware that reverse transcripts could be contained in a bacterial genome, albeit in limited number of genomes, there is no suggestion that one skilled in the art would be able to find particular reverse transcripts as described in the applicants claims.

This argument is not found persuasive because the above references teach a bacterial reverse transcriptase and methods of claims 8, 10, 15 and 16 (See also above comments regarding applicants submitted copy of claim 8).

Claims 1, 2, 4-6, 8, 15-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu et al. (Journal of Bacteriology 174(7): 2384-2387, April 1992), as applied to claims 1, 2, 4-8 and 15-17 above, and further in view of Lim and Mass (Cell 56:891-904, 1989).

The rejection is stated in the previous office actions.

Applicants have amended claims 1 and 15 in response to this rejection and traverse the rejection as it applies to the newly amended claims.

Applicants submit that as a result of the claim amendments and applicants remarks the rejection should now be obviated. With respect to applicants amendment of claims 1, 2, 4-6 and 17 that the claimed bacterial RT is encoded by SEQ ID NO: 1 (See also above 112 second paragraph rejections), this is considered an inherent property of the bacterial RT for which the original rejection was made, and motivation stated.

Applicants submit that the reference Hsu et al. merely indicates the presence of msDNA in *M. xanthus* and *E. coli* and that contrary to the examiner's assertion there is no motivation to combine the references. Applicants submit that owing to the substantial differences between these two species and their respective reverse transcripts, one skilled in the art had no motivation to combine the references and applicants present a passage from applicants specification to support applicants position. Applicants arguments continue to be non-persuasive because while applicants argue that there are distinct differences between the RT's described by Hsu et al. and the RT from *E. coli*, such does not take away from the motivation to identify and isolate the *E. coli* RT as previously stated.

As previously stated, Lim and Mass teach the reverse transcriptase dependent synthesis of a covalently linked, branched DNA-RNA compound in *E. coli* and the transformation of *E. coli* JM103 with the construct pT-14 and the encoded bacterial reverse transcriptase as determined by the synthesis of msDNA.

One of ordinary skill in the art would have been motivated to express this nucleic acid sequence to confirm Hsu et al. hypothesis that the nucleic acid encodes a protein with reverse transcriptase activity. The reasonable expectation of success comes from the high degree of knowledge in the art with respect to the expression of recombinant proteins as is demonstrated by Lim and Mass (Cell 56:891-904, 1989).

Applicants reference to the homology between *M. xanthus* and *e. coli* RT's has no bearing on the motivation to express the RT previously partially isolated by Lim and Mass. As previously stated, Lim and Mass were in possession of encoded *E. coli*

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bacterial reverse transcriptase as determined by the synthesis of mSDNA and thus the degree of similarity to those RT's described by Hsu et al. is considered irrelevant.

Remarks

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a long horizontal flourish extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rg
12/18/2003